Remarks

The claims are being amended as required by the Examiner. (The change to claim 24 is slightly different from that requested by the Examiner; it is believed the Examiner intended the change that has been made.) With respect to the § 101 rejection, applicants are amending claims 1 and 25 to recite the apparatus that applies the breathable gas at positive pressure. It is believed that applicants have overcome all of the formal objections of the Examiner.

With respect to the Examiner's question concerning claims 11 and 23, since the thresholds reference different parameters, the thresholds do not necessarily bear any relationship to each other.

The main prior art reference is Stahmann Publication No. 2005/0115561. Before distinguishing the claims from the reference, it will be helpful to review the subject invention.

The key feature of the invention is the use of two control loops. The outer "macro" loop controls the inner "micro" loop. It is the inner loop that exercises the "hands-on" control of the machine, looking for an "error" (a deviation from some target or desired value) and making an instantaneous adjustment to eliminate the error. The outer loop does not look for the instantaneous error that controls the inner loop. Instead, it looks for a different error and in response to that error causes a change in how the inner loop operates.

For example, the outer loop may determine an arousal index (which is compared to an outer-loop target) that reflects how often the patient was aroused the night before. The inner loop has a different target parameter (e.g., ventilation) and depending on the arousal index value the inner loop is made more or less sensitive to errors in desired ventilation or the inner loop may be made to provide a more or less aggressive treatment. It is not practical to use the long-term arousal index of the outer loop as the "hands-on" control parameter of the inner loop because there would be too long a lag in responding to errors.

Contrast this with a typical control mechanism in which the average ventilation over a few minutes might be determined, and an adjustment might be made if the

ventilation over a few seconds differs from the minutes-long average. The parameter being controlled here (ventilation) is used to determine both the desired value for the control loop (the average over a few minutes) and whether there is an instantaneous error. There is really only one control loop, the one for adjusting the instantaneous ventilation. The target value (average over a few minutes) is calculated but has no control loop associated with it. Whatever average value is determined is the value used in the single control loop. There is no value that is set or determined outside the control loop. There is just one control loop, and the target that is used to measure the error is calculated as a function of the loop operation (the minutes-long average value of the ventilation that is being controlled).

On the other hand, in the invention there are indeed two separate control loops. The outer loop in the illustrative embodiment looks for how often the patient was aroused the night before. Depending on the value determined (compared with some predetermined reference), the inner "instantaneous" control loop has its operation changed (by way of sensitivity or aggressiveness). This has the effect, hopefully, of affecting the outer macro control loop such that the arousal index returns to the predetermined reference value. The parameter that is set by the outer loop (sensitivity or aggressiveness) for controlling operation of the inner loop need not be the parameter that is actually controlled by the inner loop, as distinguished from the more common example discussed above in which ventilation is the parameter that determines the target value (average over a few minutes) and is also the parameter that is controlled by the instantaneous control loop.

Applicants have not found in Stahmann the use of two control loops, one inner and one outer (the latter affecting how the former operates). That is a basic distinguishing feature of the invention and it is just not disclosed in Stahmann.

Starting on page 7 of the Office Action, the Examiner cites particular paragraphs of Stahmann that are said to disclose respective claim elements. The Examiner first cites five paragraphs that refer to measuring an arousal index. (An arousal index is just one measure of Stahmann's broader measure of sleep disordered breathing, and while the following discussion refers to an arousal index because the Examiner focused on this measure of error, the argument applies to other measures of sleep disordered breathing as

well.) The Examiner is absolutely correct that Stahmann calculates an arousal index. But the Examiner is incorrect in saying that the arousal index is determined "in an outer loop of a control algorithm." Stahmann has just one control loop, and it operates both to determine how far the arousal index is away from a desired value (the error) and to change a control parameter that tends to return the arousal index to the desired value.

The next twelve paragraphs cited by the Examiner are said to disclose monitoring airflow in an inner loop to detect an obstruction and to adjust sensitivity or aggressiveness of treatment so as to change the arousal index. But these paragraphs really distinguish the invention from Stahmann rather than supporting the Examiner's argument. Some parameter is controlled in a feedback loop in Stahmann to bring the arousal index back to an acceptable value. This is not the claimed invention. Stahmann has just one control loop. The target is some value of arousal index. Some parameter is controlled in a feedback loop so as to bring the arousal index back to a desired value. But the arousal index is the only target because Stahmann has only one control loop. In the invention, on the other hand, there are two control loops and two targets (e.g., an arousal index value for the outer loop and a ventilation value for the inner loop). Paragraph [0739] cited by the Examiner is an example of what applicants mean when they say that the Examiner's cites actually support their position. This paragraph makes it clear that there is only one control loop in which the applied therapy (cardiac, in this case) adjusts the arousal index.

The above remarks apply to independent claims 1 and 13. With respect to their dependent claims and the Examiner's references to other paragraphs in Stahmann, all of these claims define the inner and outer loops of their respective independent claims, and this key feature of the invention is just not to be found in Stahmann.

Claims 25 and 49 are admittedly broader, but they also define two control loops that are just not to be found in Stahmann. In regard to each of these claims, the Examiner cites paragraph [0454] of Stahmann. But this paragraph epitomizes applicants' basic argument. Stahmann says here that if sleep disordered breathing (exemplified, for example, by an arousal index) is detected, then therapy (for example, cardiac pacing) is delivered to mitigate it. This paragraph is talking about a single control loop, while the

claims require two control loops, one inner and one outer. The Stahmann material relied upon by the Examiner proves applicants' case.

Again, with respect to the claims that are dependent on independent claims 25 and 49, the Examiner's references to other paragraphs in Stahmann do not change the fact that all of these claims define the inner and outer loops of their respective independent claims, and this key feature of the invention is just not to be found in Stahmann.

The Examiner rejected some of the claims as being unpatentable over Stahmann in view of Axe (Patent No. 5,458,137) or Wickham (Publication No. 2007/0084464). But it is Stahmann in all cases that is said to disclose the two control loops, and Axe or Wickham is relied on only for a dependent feature. Because Stahmann does not disclose the two control loops for the reasons given, the combined references do not suggest the claimed invention.

Applicants appreciate the Examiner having indicated that many of the dependent claims define patentable subject, it following that such claims would be allowed if written in independent form. However, it is believed that the independent claims are clearly allowable over the cited prior art, and therefore the dependent claims are not being rewritten in independent form.

The other references cited by the Examiner have been reviewed but are not believed to be relevant to applicants' invention as claimed. In view of the above remarks, it is requested that all claims remaining in the application be allowed and the application passed to issue as soon as possible.

Respectfully submitted,

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